REMARKS -- TABLE OF CONTENTS

I. STATUS OF CLAIMS

Claims 1-34 are pending and claims 35-65 are withdrawn from consideration.

Claims 1-4, 6-9, 17, 20-21, and 25-34 stand rejected under 35 U.S.C. 102(b) as being anticipated by Lebel (U.S. Patent Application 20020065509) *See Examiner's Office Action,* p. 2 (06 September 2007).

Claims 1-3, 5, 10-11, 13-16, 23-26, and 34 stand rejected under 35 U.S.C. 102(b) as being anticipated by O'Leary (U.S. Patent 6,384,741) *See Examiner's Office Action,* p. 3 (06 September 2007).

Claims 1-4, 8-9, 17, 20-21 and 25-33 stand rejected under 35 U.S.C. 102(b) as being anticipated by Labbe (U.S. Patent 4,944,659) *See Examiner's Office Action,* p. 3 (06 September 2007).

Claims 1, 10, 12, and 18-19 stand rejected under 35 U.S.C. 102(b) as being anticipated by Davison (U.S. Patent 6,296,638) *See Examiner's Office Action,* p. 3 (06 September 2007).

Claims 1 and 22 stand rejected under 35 U.S.C. 102(b) as being anticipated by Adair (U.S. Patent 6,086,528) *See Examiner's Office Action,* p. 3 (06 September 2007).

Claims 1-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-37 of copending Application No. 10/827,576. *See Examiner's Office Action,* p. 4 (06 September 2007).

Claims 1-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-41 of copending Application No. 10/827,390. *See Examiner's Office Action,* p. 4 (06 September 2007).

II. ISSUES TO BE REVIEWED

The issues in this response relate to whether the art of record establishes a *prima facie* case of the unpatentability of Applicant's Claims 1-34. For reasons set forth elsewhere herein, Applicant respectfully asserts that the art of record does not establish a *prima facie* case of the unpatentability of any pending claim. Accordingly, Applicant respectfully requests that

Examiner hold all pending Claims 1-34 allowable for at least the reasons described herein, and issue a Notice of Allowance on same.

III. ARGUMENT: ART OF RECORD DOES NOT ESTABLISH *PRIMA FACIE* CASE OF UNPATENTABILITY IN VIEW OF CITED ART OF RECORD

Examiner has stated "Claims 1-4, 6-9, 17, 20-21, and 25-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Lebel (20020065509)" ("Lebel" hereinafter) *See Examiner's Office Action,* p. 2 (06 September 2007); Examiner has stated "Claims 1-3, 5, 10-11, 13-16, 23-26 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Leary (6,384,741)" ("O'Leary" hereinafter) *See Examiner's Office Action,* p. 2 (06 September 2007); Examiner has stated "Claims 1-4, 8-9, 17, 20-21, and 25-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Labbe (4,944,659)" ("Labbe" hereinafter) *See Examiner's Office Action,* p. 2 (06 September 2007); Examiner has stated "Claims 1, 10, 12, 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Davison (6,296,638)" ("Davison" hereinafter) *See Examiner's Office Action,* p. 2 (06 September 2007); and "Claims 1 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Adair (6,086,528)" ("Adair" hereinafter) *See Examiner's Office Action,* p. 4 (06 September 2007).

In response, Applicant respectfully asserts herein that, under the MPEP and legal standards for patentability as set forth below, the art of record does not establish a *prima facie* case of the unpatentability of Applicant's claims at issue. Specifically, Applicant respectfully shows below that the art of record does not recite the text of Applicant's claims at issue, and hence fails to establish a *prima facie* case of unpatentability. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejections and hold all claims to be allowable over the art of record.

A. MPEP Standards for Patentability[1]

The MPEP states as follows: "the examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant. . . If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent." *MPEP* § 2107 (citing *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992)); *In Re Glaug*, 283 F.3d 1335, 62 USPQ2d 1151 (Fed. Cir. 2002) ("During patent examination the PTO bears the initial burden of presenting a *prima facie* case of unpatentability. *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 U.S.P.Q. 785, 788 (Fed. Cir. 1984). If the PTO fails to meet this burden, then the applicant is entitled to the patent."). "Contrary to appellant's reasoning, after the PTO establishes a prima facie case of anticipation based on inherency, the burden shifts to appellant to 'prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.'" *In re William J. King*, 801 F.2d 1324; 231 U.S.P.Q. 136 (Fed. Cir. 1986). Accordingly, unless and until an examiner presents evidence establishing *prima facie* unpatentability, an applicant is entitled to a patent on all claims presented for examination.

1. MPEP Standards for Determining Anticipation

An examiner bears the initial burden of factually supporting any *prima facie* conclusion of anticipation. *Ex Parte Skinner*, 2 U.S.P.Q.2d 1788, 1788-89 (B.P.A.I. 1986); *In Re King*, 801 F.2d 1324, 231 U.S.P.Q. (BNA) 136 (Fed. Cir. 1986); *MPEP* § 2107 (citing *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992) ("[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability....")). Failure of an examiner to meet this burden entitles an applicant to a patent.

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[1] Applicant is aware that Examiner is familiar with the MPEP standards. Applicant is merely setting forth the MPEP standards to serve as a framework for Applicant's arguments following and to ensure a complete written record is established. Should Examiner disagree with Applicant's characterization of the MPEP standards, Applicant respectfully requests correction.

Id. ("[i]f examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent").

The MPEP indicates that in order for an examiner to establish a *prima facie* case of anticipation of an applicant's claim, the examiner must first interpret the claim,[2] and thereafter show that the cited prior art discloses the same elements, in the same arrangement, as the elements of the claim which the examiner asserts is anticipated. More specifically, the MPEP states that "[a] claim is anticipated *only if each and every element as set forth in the claim is found*, either expressly or inherently described, in a single prior art reference. . . . The identical invention must be shown in as complete detail as is contained in the . . . claim. . . . The elements must be arranged as required by the claim . . . .". *MPEP* § 2131 (emphasis added). Consequently, under the guidelines of the MPEP set forth above, if there is *any* substantial difference between the prior art cited by an examiner and an applicant's claim which the examiner asserts is rendered anticipated by the prior art, the prior art does NOT establish a *prima facie* case of anticipation and, barring other rejections, the applicant is entitled to a patent on such claim.

2. MPEP Standards for Determining Obviousness

"[T]he examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness."[3] *MPEP* § 2142. The MPEP indicates that in order for an examiner to establish a *prima facie* case that an invention, as defined by a claim at issue, is obvious, the examiner must (1) interpret the claim at issue; (2) define one or more prior art reference components relevant to the claim at issue; (3) ascertain the differences between the one or more prior art reference components and the elements of the claim at issue; and (4) adduce objective

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[2] With respect to interpreting a claim at issue, the MPEP directs that, during examination -- as opposed to subsequent to issue -- such claim be interpreted as broadly as the claim terms would reasonably allow, in light of the specification, when read by one skilled in the art with which the claimed invention is most closely connected. *MPEP* § 2111.

[3] An invention, as embodied in the claims, is rendered obvious if an examiner concludes that although the claimed invention is not identically disclosed or described in a reference, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *MPEP* § 2141 (citing 35 U.S.C. § 103).

evidence which establishes, under a preponderance of the evidence standard, a teaching to modify the teachings of the prior art reference components such that the prior art reference components can be used to construct a device substantially equivalent to the claim at issue. This last step generally encompasses two sub-steps: (1) adducement of objective evidence teaching how to modify the prior art components to achieve the individual elements of the claim at issue; and (2) adducement of objective evidence teaching how to combine the modified individual components such that the claim at issue, as a whole, is achieved. *MPEP* § 2141; *MPEP* § 2143. Each of these forgoing elements is further defined within the MPEP. *Id.*

This requirement has been explained recently by the Supreme Court in *KSR v. Teleflex, 550 U.S. _____; 127 S. Ct. 1727 (2007)* which noted that such a rejection requires "some articulated reasoning ... to support the legal conclusion of obviousness." As stated by the Court, obviousness can be established where "there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, ***this analysis should be made explicit.***" (*emphasis added*) See In re Kahn, 441 F. 3d 977, 988 (CA Fed. 2006) ('[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.')." *KSR v. Teleflex, 550 U.S. _____; 127 S. Ct. 1727 at 1741.*

As further described by the Court ***"[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.*** Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *KSR v. Teleflex, 550 U.S. _____; 127 S. Ct. 1727 at 1741.*

a) Interpreting a Claim at Issue

With respect to interpreting a claim at issue, the MPEP directs that, during examination -- as opposed to subsequent to issue -- such claim be interpreted as broadly as the claim terms

would reasonably allow when read by one skilled in the art with which the claimed invention is most closely connected. In practice, this is achieved by giving each of the terms in the claim the "plain meaning" of the terms as such would be understood by those having ordinary skill in the art, and if portions of the claim have no "plain meaning" within the art, or are ambiguous as used in a claim, then the examiner is to consult the specification for clarification. *MPEP* § 2111.

b) Definition of One or More Prior Art Reference Components Relevant to the Claim at Issue

Once the claim at issue has been properly interpreted, the next step is the definition of one or more prior art reference components (*e.g.*, electrical, mechanical, or other components set forth in a prior art reference) relevant to the properly interpreted claim at issue. With respect to the definition of one or more prior art reference components relevant to the claim at issue, the MPEP defines three proper sources of such prior art reference components, with the further requirement that each such source must have been extant at the time of invention to be considered relevant. These three sources are as follows: patents as defined by 35 U.S.C. § 102, printed publications as defined by 35 U.S.C. § 102, and information (*e.g.*, scientific principles) deemed to be "well known in the art"[4] as defined under 35 U.S.C. § 102. *MPEP* § 2141; *MPEP* § 2144.

c) Ascertainment of Differences between Prior Art Reference Components and Claim at Issue; Teaching to Modify and/or Combine Prior Art Reference Components to Remedy Those Differences in Order to Achieve Recitations of Claim at Issue

With one or more prior art components so defined and drawn from the proper prior art sources, the differences between the one or more prior art reference components and the elements

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[4] The fact that information deemed to be "well known in the art" can serve as a proper source of prior art reference components seems to open the door to subjectivity, but such is not the case. As a remedy to this potential problem, *MPEP* § 2144.03 states that if an examiner asserts that his position is derived from and/or is supported by a teaching or suggestion that is alleged to have been "well known in the art," and that if an applicant traverses such an assertion (that something was "well known within the art"), the examiner must cite a reference in support of his or her position. The same MPEP section also states that when a rejection is based on facts within the personal knowledge of an examiner, the data should be stated as specifically as possible, and the facts must be supported, when called for by the applicant, by an affidavit from the examiner. Such an affidavit is subject to contradiction or explanation by the affidavits of the applicant and other persons. *Id.* Thus, all sources of prior art reference components must be objectively verifiable.

of the claim at issue are to be ascertained. Thereafter, in order to establish a case of *prima facie* obviousness, an examiner must set forth a rationale, supported by objective evidence[5] sufficient to demonstrate under a preponderance of the evidence standard, that in the prior art extant at the time of invention there was a teaching to modify and/or combine the one or more prior art reference components to construct a device practicably equivalent to the claim at issue.

The preferable evidence relied upon is an express teaching to modify/combine within the properly defined objectively verifiable sources of prior art. In the absence of such express teaching, an examiner may attempt to establish a rationale to support a finding of such teaching reasoned from, or based upon, express teachings taken from the defined proper sources of such evidence (*i.e.*, properly defined objectively verifiable sources of prior art). *MPEP* § 2144; *In re Dembiczak*, 50 U.S.P.Q.2d 1614 (Fed. Cir. 1999).

The MPEP recognizes the pitfalls associated with the tendency to subconsciously use impermissible "hindsight" when an examiner attempts to establish such a rationale. The MPEP has set forth at least two rules to ensure against the likelihood of such impermissible use of hindsight. The first rule is that:

> under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information,[6] the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. Knowledge of an Applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search, and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon an Applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

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[5] The proper sources of the objective evidence supporting the rationale are the defined proper sources of prior art reference components, discussed above, with the addition of factually similar legal precedent. *MPEP* § 2144.

[6] "Factual information" is information actually existing or occurring, as distinguished from mere supposition or opinion. *Black's Law Dictionary* 532 (5th ed. 1979).

MPEP § 2142 (emphasis added). Thus, if the only objective evidence of such teaching to modify and/or combine prior art reference components is an applicant's disclosure, no evidence of such teaching exists.[7]

The second rule is that if an examiner attempts to rely on some advantage or expected beneficial result that would have been produced by a modification and/or combination of the prior art reference components as evidence to support a rationale to establish such teachings to modify and/or combine prior art reference components, the MPEP requires that such advantage or expected beneficial result be objectively verifiable teachings present in the acceptable sources of prior art (or drawn from a convincing line of reasoning based on objectively verifiable established scientific principles or teachings). *MPEP* § 2144. Thus, as a guide to avoid the use of impermissible hindsight, these rules from the MPEP make clear that absent some objective evidence, sufficient to persuade under a preponderance of the evidence standard, no teaching of such modification and/or combination exists.[8]

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[7] An applicant may argue that an examiner's conclusion of obviousness is based on improper hindsight reasoning. However, "[a]ny judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." *MPEP* § 2145(X)(A) (emphasis added).

[8] *In Re Sang Su Lee* 277 F.3d 1338 (Fed. Cir. 2002) ("When patentability turns on the question of obviousness, the search for and analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness.") *See, e.g., McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1351-52, 60 U.S.P.Q.2d 1001, 1008 (Fed. Cir. 2001) ("the central question is whether there is reason to combine [the] references," a question of fact drawing on the *Graham* factors). *"The factual inquiry whether to combine references must be thorough and searching." Id. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with. See, e.g., Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1124-25, 56 U.S.P.Q.2d 1456, 1459 (Fed. Cir. 2000) ("a showing of a suggestion, teaching, or motivation to combine the prior art references is an 'essential component of an obviousness holding'") (quoting *C.R. Bard, Inc., v. M3 Systems, Inc.*, 157 F.3d 1340, 1352, 48 U.S.P.Q.2d 1225, 1232 (Fed. Cir. 1998)); *In re Dembiczak*, 175 F.3d 994, 999, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999) ("Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references."); *In re Dance*, 160 F.3d 1339, 1343, 48 U.S.P.Q.2d 1635, 1637 (Fed. Cir. 1998) (there must be some motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the applicant); *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988) ("'teachings of references can be combined only if there is some suggestion or incentive to do so.'") (emphasis in original) (quoting *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984)). The need for specificity pervades this authority. *See, e.g., In re Kotzab*, 217 F.3d 1365, 1371, 55 U.S.P.Q.2d 1313, 1317 (Fed. Cir. 2000) ("particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed"); *In re Rouffet*, 149 F.3d 1350, 1359, 47 U.S.P.Q.2d 1453, 1457-58 (Fed. Cir. 1998) ("even when the level of skill in the art is high, the Board must identify specifically the principle, known to one of ordinary skill, that suggests the claimed combination. In other words, the Board must explain the reasons one of ordinary skill in the

B. Technical Material Cited by Examiner (Lebel (U.S. Published Patent No.: 20020065509)) Does Not Recite the Text of Independent Claim 1 as Presented Herein; Notice of Allowance of Same Respectfully Requested

1. Independent Claim 1

Independent Claim 1 recites: "A device for perfusion management, comprising: a body portion; at least one extensible finger coupled to said body portion; at least one reservoir in communication with said extensible finger; and a control circuitry coupled to said extensible finger, and/or said body portion."

a) Technical Material Cited by Examiner Does Not Recite the Text of at Least Independent Claim 1.

As set forth above, Independent Claim 1 recites as follows: A device for perfusion management, comprising: [a] a body portion; [b] at least one extensible finger coupled to said body portion; [c] at least one reservoir in communication with said extensible finger; and [d] a control circuitry coupled to said extensible finger, and/or said body portion.[9]

With respect to Claim 1, Examiner has stated, "Claims 1-4, 6-9,17,20-21, and 25-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Lebel et al (USPubN 20020065509). Lebel discloses an implantatable system that includes drug delivery and sensory monitoring of the patient, among other features. The system includes a body portion, an extending part, at least one receiving part and control circuitry. The system also includes a pump, sensors, wireless communication components, insulin and processor. See figures 1B and 3-5." Examiner's Office Action, p. 2 (06 September 2007).

(1) Examiner Citations With Regard to Clause [b] of Independent Claim 1:

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art would have been motivated to select the references and to combine them to render the claimed invention obvious.")).

[9] The lettering of the clauses herein is merely for sake of clarity of argument and should not be taken to imply any particular ordering of the clauses.

Applicant respectfully points out that Applicant has reviewed the portions of Lebel identified by Examiner, and so far as Applicant can discern, Lebel does not recite the text of clause [b] of Applicant's Independent Claim 1. Rather, Figure 1B of Lebel cited by Examiner recites as follows:

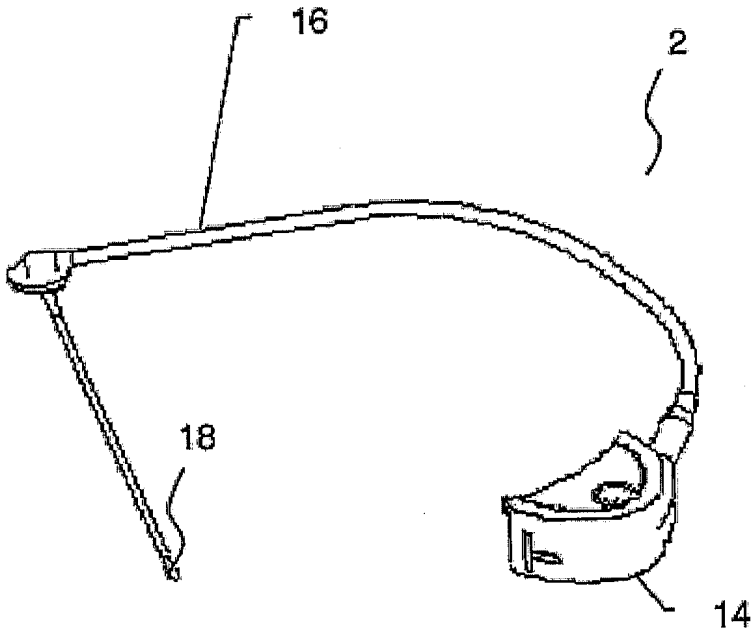


FIGURE 1B

Applicant respectfully points out that the corresponding portion of Lebel's Specification recites:

> [0137] The outer appearance of the implantable device 2 is depicted in two pieces in FIGS. 1a and 1b and includes housing 6 having a drug outlet port 8, and a refill port 12, a removable sideport 14 that mounts against the side of the housing 6 over outlet port 8, and a catheter 16 having a distal end 18 and a proximal end that attaches to sideport 14. In alternative embodiments, the implantable device may take on a different shape and/or the sideport may be removed in favor of a permanently mounted catheter assembly.

Figures 3 and 4 of Lebel cited by Examiner recites as follows:

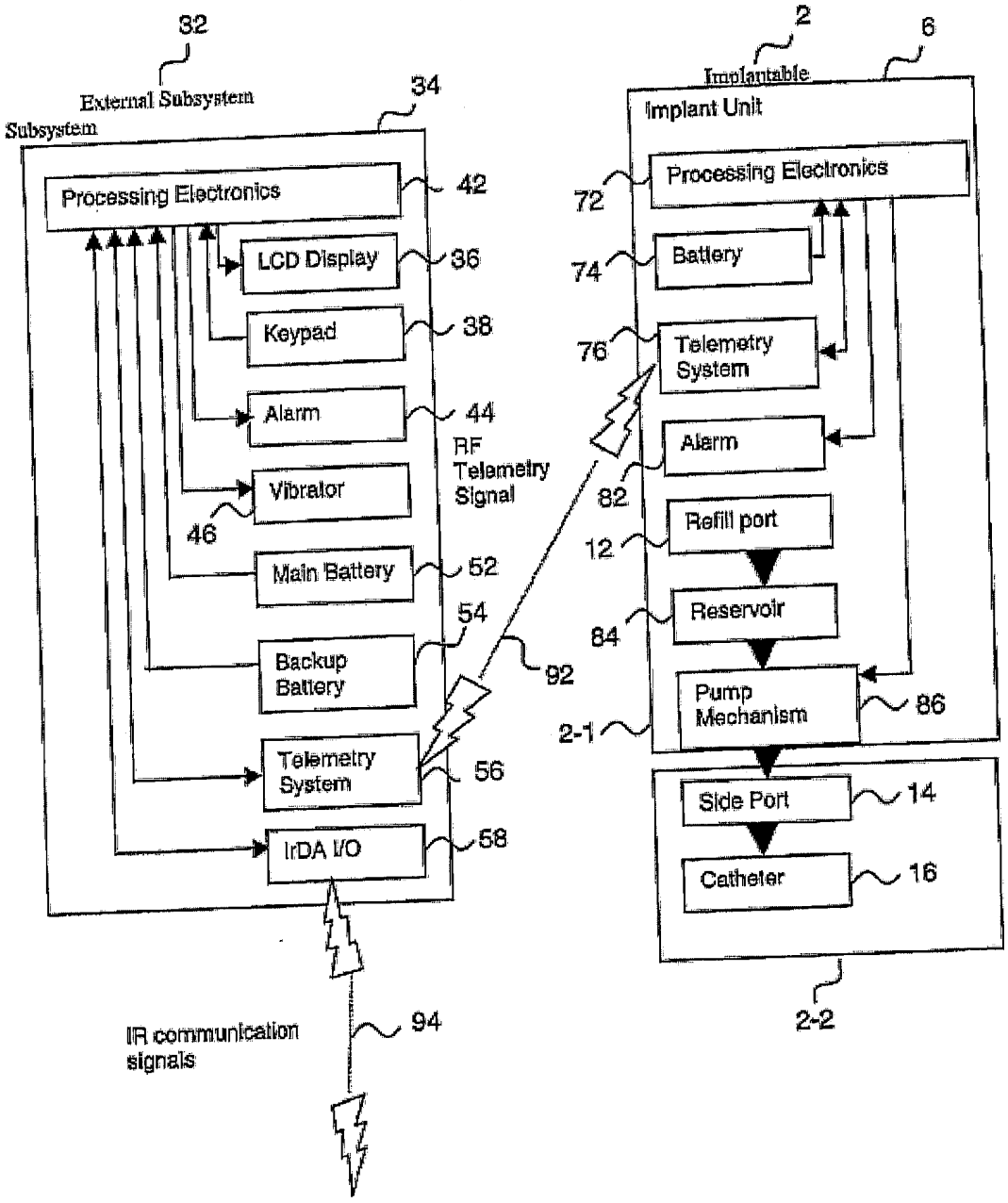


FIGURE 3

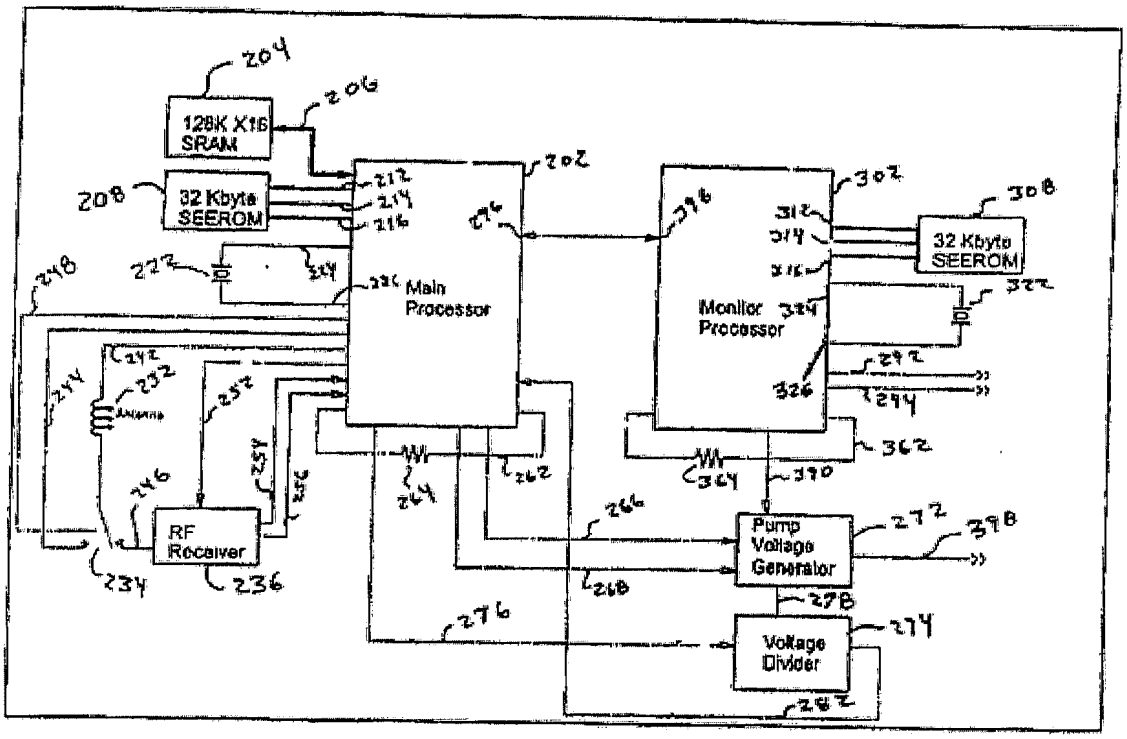


FIGURE 4

Applicant respectfully points out that the corresponding portion of Lebel's Specification recites:

> [0202] FIG. 3 depicts a simplified block diagram of various functional components or modules (i.e. single components or groups of components) included in the implantable medical device 2 and external communication device 32. The external communication device 32 includes (1) a housing or cover 34 preferably formed from a durable plastic material, (2) processing electronics 42 including a CPU and memory elements for storing control programs and operation data, (3) an LCD display 36 for providing operation for information to the user, (4) a keypad 38 for taking input from the user, (5) an audio alarm 44 for providing information to the user, (6) a vibrator 46 for providing information to the user, (7) a main battery 52 for supplying power to the device, (8) a backup battery 54 to provide memory maintenance for the device, (9) a radio frequency (RF) telemetry system 56 for sending signals to the implantable medical device and for receiving signals from the implantable medical device, and (10) an infrared (IR) input/output system 58 for communicating with a second external device.

[0206] As depicted in FIG. 3, the implantable device includes a reservoir 84 for holding a desired quantity of insulin. In this embodiment, the drug held in the reservoir is preferably maintained at a slight negative differential pressure (with respect to the pressure on the outside of the housing) so that in the event of a leakage in the reservoir 84 or housing 6, the drug will not be forced from the housing into the body of the patient. The drug is added to the reservoir 84 by means of a transcutaneous needle that is passed from a position exterior to the body into self sealing refill port 12. Due to the slight negative pressure that the reservoir experiences, insulin in a syringe connected to the needled is drawn into the reservoir without need of external force. The drug is extracted from the reservoir 84 and forced through catheter 16 by an electronically controlled pump mechanism 86. In alternative embodiment positive pressure reservoirs may be used in combination with pumping mechanisms that force the medication or drug from the implantable device and/or used with flow restrictors that dispensed the drug at a fixed rate or at a variable rate with the aid of valves or flow diverters.

[0224] The main processor 202 is functionally connected to an SRAM Module 204 by address, data, and control lines 206. The external SRAM 256 provides 256 kbytes of memory. A preferred SRAM module is configured to operate between 2.3 and 3.3 volts, to consume no more than 10 uA during standby, and more preferably no more than about 2 uA.

[0240] The main processor additionally provides an activate signal to control a switch (e.g. a MOSFET) within a voltage divider circuit 274, by line 276, to activate the divider circuit which in turn receives a voltage level input on line 278 from the pump voltage generator circuit 272 and provides a reduced voltage signal on line 282 back to an analog-to-digital converter (ADC) input on the main processor so as to enable a pump circuit voltage measurement and analysis to be made.

[0241] The monitor processor 302 is functionally connected to a SEEPROM 308 of the same type as used in conjunction with the main processor 202 and is connected thereto in an analogous manner using power line 312, clock line 314, and data line 316.

[0242] The monitor processor is also functionally connected to an external crystal oscillator 322 of the same type as used in conjunction with the main processor by lines 324 and 326.

[0243] The monitor processor further supplies two power lines 292 and 294 that carry two power signals to a buzzer. The signals are output to a connector on the hybrid board. The signals are then carried by cable to a piezo electric buzzer that is mounted to an inside wall of the housing 6.

[0244] The monitor processor also provides an external line 362 that carries a reset signal from an internal watchdog circuit output to an external reset

input. Line 362 includes a resister 364 (e.g. 10 kΩ resistor) to condition a signal being transmitted along the line.

[0245] The monitor processor additionally provides a firing signal by line 390 to the pump voltage generator circuit when it is time to activate the pump mechanism. The pump voltage generator 272 provides two lines 398 that connect to the pumping mechanism located off the hybrid circuit so as to allow current to flow through the coil of the pumping mechanism when a firing command is given by the monitor processor.

[0246] The pump voltage generator 272 charges two large capacitors within the pump voltage generator module 272 to approximately 16 Volts. The capacitors are about 22 μF each thereby providing an effective capacitance of 44 μF. Upon receipt of a fire signal on line 390 from the monitor processor, the pump circuit discharges the capacitors through the pump coil via two lines 398 to initiate the pump action.

[0247] The capacitor charge operation is controlled by two signals generated by the main processor. A pump power signal on line 266 activates a transistor switch (not shown) enabling power (nominally at 3 volts) to reach a charging inductor (not shown). A pump clock signal on line 268 completes the rest of the circuit by activating a second transistor switch (not shown) in a pulsed manner thereby allowing pulsed current to flow through inductor 618. As transient current is pulsed through the inductor, a higher voltage than the nominal amount supplied is developed which is bled into a charging bank containing the two capacitors noted above. Back flow of built up current is inhibited by a diode. A clock rate of about 60-70 kHz (e.g. about 216 Hz) is used for modulating the second transistor. The capacitor bank provides one output to an inductive coil of the electromagnetic pump mechanism. A lead returns from the other end of the pump mechanism and passes through a third transistor switch before reaching a ground line on the hybrid board. When the third switch is in an open state (deactivated), the charge in the capacitor bank is inhibited from reaching ground. The previously mentioned firing signal on line 390 from the monitor processor causes selective activation of the third switch and thus enables the capacitor bank to discharge itself through the inductive coil of the pump. The third switch is preferably a power field effect transistor (FET) with a very small "on" resistance (e.g. about 0.05 Ω or less). The pump capacitors are protected against over-charging by a Zener diode having a maximum voltage of about 21 volts.

[0248] The main and monitor processors include serial input and output ports 296 and 396 respectively. The main and monitor processors communicate through a first bi-directional, hardwired, six wire synchronous serial interface through these ports. Two signals, data and clock, are used to transfer information from the main processor IC to the monitor processor IC. Two signals, data and clock, transfer information from the monitor processor IC to the main processor IC. Read and clear signals provide for handshake between the main and the

monitor processor ICs. The interface clock frequency is half the crystal oscillator frequency.

[0249] The hybrid circuit is preferably powered by a battery 402 that provides a voltage between about 2.3 volts to about 3.6 volts. A preferred battery is a lithium(anode) carbon monofluoride (cathode) battery having an initial capacity of preferably more than about 2600 mA-Hr while maintaining a loaded output voltage of at least 2.4 volts when drawing a 6 mA current. A preferred battery is Model No. 9646 from Wilson Greatbatch, Ltd. of Clarence, N.Y.

Figure 5 of Lebel cited by Examiner recites as follows:

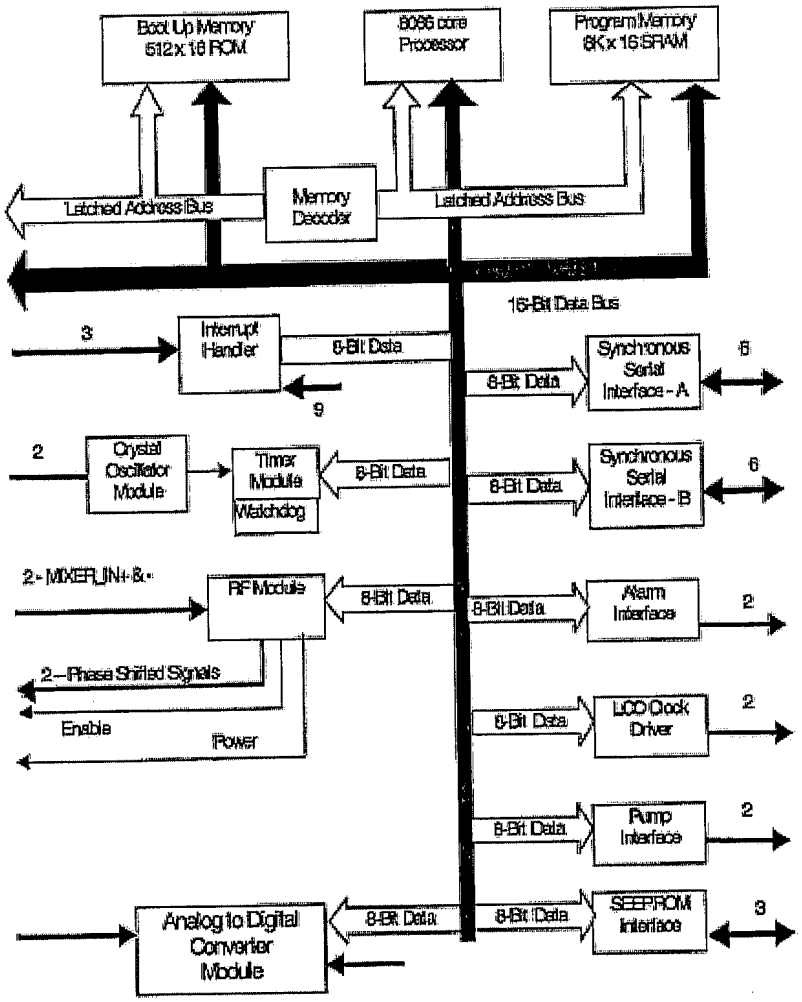


Figure 5

Applicant respectfully points out that the corresponding portion of Lebel's Specification discloses:

> [0211] A functional block diagram of the Processor IC for the present embodiment is depicted in FIG. 5. Each processor IC of the present embodiment includes a CPU 912 and various peripheral modules that are used for system control, data acquisition, and interfacing with electrical components external to the processor IC.
>
> [0212] The peripheral modules of the processor IC of the present embodiment include (1) a non-volatile memory interface module, e.g. a SEEPROM interface module 914, (2) a boot ROM module 916; (3) an SRAM module 918; (4) a memory decoder module 920; (5) a crystal oscillator module 922; (6) a timer module 924; (7) a pump interface module 926; (8) a watchdog module 928; (9) an RF telemetry module 930; (10) an interrupt handler module 932; (12) an analog-to-digital converter module 934; (13) an LCD clock driver module 936; (14) an alarm interface module 938; and (15) first and second synchronous serial interface modules 942 and 944. The memory decoder module interfaces with the core processor, boot ROM, and internal SRAM using a 16 bit address bus which also is available off chip for addressing external memory. With the exception of the crystal oscillator module all other internal module communicate over an 8-bit data bus or 16-bit data bus. FIG. 6 further illustrates that the A/D module may take input from sources internal to the processor IC and similarly the interrupt handler can take up to 9 interrupts from sources internal to the processor IC. Additionally, most of the modules communicate with outside components or modules over one or more input/output lines.
>
> [0223] A block diagram for the hybrid circuit in the implantable device is shown in FIG. 5. The hybrid circuit includes, among other things, a first processor IC designated as the main processor 202 and a second processor, designated as the monitor processor 302. In this embodiment, the main processor 202 and monitor processor 302 are identical.

See Lebel (U.S. Published Patent Application, Figs. 1B, and 3-5, Paras. 137, 202, 206, 211-212, 223-224, and 240-249).

As can be seen from the foregoing, the Examiner-identified portions of Lebel do *not recite* the text of clause [b] as recited in Independent Claim 1. For example, clause [b] recites "at least one extensible finger."

Applicant has reviewed the Examiner-cited portions of Lebel and is unable to locate a recitation of clause [b] of Claim 1. Applicant further respectfully points out that the Examiner

has provided no evidence or reason as to why the text of the reference passages should be interpreted to teach clause [b] of Independent Claim 1 as the Examiner alleges.

Given that Applicant has shown, above, what Lebel actually recites, the question thus naturally arises as to how Examiner saw Lebel as teaching clause [b] of Independent Claim 1.

Applicant respectfully points out that the Applicant's Application is the only objective examiner-cited document of record that shows or suggests what Examiner purports the reference to teach. From this and Lebel's express recitations (see above), it follows that Examiner is interpreting Lebel through the lens of Applicant's application, which is impermissible hindsight use. Thus, at present, Examiner's assertions regarding Lebel are untenable.

Accordingly, under the MPEP standards as set forth above, the Examiner has not established a prima facie case that art of record anticipates Independent Claim 1. Applicant respectfully asks Examiner to hold Independent Claim 1 allowable and to issue a Notice of Allowance of same.

2. Dependent Claims 2-4, 6-9, 17, 20-21 and 25-34 Patentable for at Least Reasons of Dependency from Independent Claim 1

Claims 2-4, 6-9, 17, 20-21, and 25-34 depend either directly or indirectly from Independent Claim 1. "A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers." *See* 35 U.S.C. § 112 paragraph 4. Consequently, Dependent Claims 2-4, 6-9, 17, and 25-34 are patentable for at least the reasons why Independent Claim 1 is patentable. Accordingly, Applicant respectfully requests that Examiner hold Dependent Claims 2-4, 6-9, 17, 20-21, and 25-34 patentable for at least the foregoing reasons, and issue a Notice of Allowance on same.

C. Technical Material Cited by Examiner (O'Leary (U.S. Patent No.: 6,384,741)) Does Not Recite the Text of Independent Claim 1 as Presented Herein; Notice of Allowance of Same Respectfully Requested

1. Independent Claim 1

Independent Claim 1 recites: "A device for perfusion management, comprising: a body

portion; at least one extensible finger coupled to said body portion; at least one reservoir in communication with said extensible finger; and a control circuitry coupled to said extensible finger, and/or said body portion."

a) Technical Material Cited by Examiner Does Not Recite the Text of at Least Independent Claim 1.

As set forth above, Independent Claim 1 recites as follows: A device for perfusion management, comprising: [a] a body portion; [b] at least one extensible finger coupled to said body portion; [c] at least one reservoir in communication with said extensible finger; and [d] a control circuitry coupled to said extensible finger, and/or said body portion.[10]

With respect to Claim 1, Examiner has stated, "Claims 1-3, 5, 10-11, 13-16, 23-26 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Leary et al (USPN 6,384,741 Bl). O'Leary discloses a motorized extendable/retractable antenna for viewing traffic obscured by large vehicles. The system includes a body (car), an extending part (antenna), a receiving part (antenna housing within car), multiple control circuits, a camera, and rotator for the camera. The antenna is telescopic. See figures." Examiner's Office Action, p. 3 (06 September 2007).

(1) Examiner Citations With Regard to Clause [c] of Independent Claim 1:

Applicant respectfully points out that Applicant has reviewed the portions of O'Leary identified by Examiner, and so far as Applicant can discern, O'Leary does not recite the text of clause [c] of Applicant's Independent Claim 1. Rather, the figures of O'Leary cited by Examiner recite as follows:

[10] The lettering of the clauses herein is merely for sake of clarity of argument and should not be taken to imply any particular ordering of the clauses.

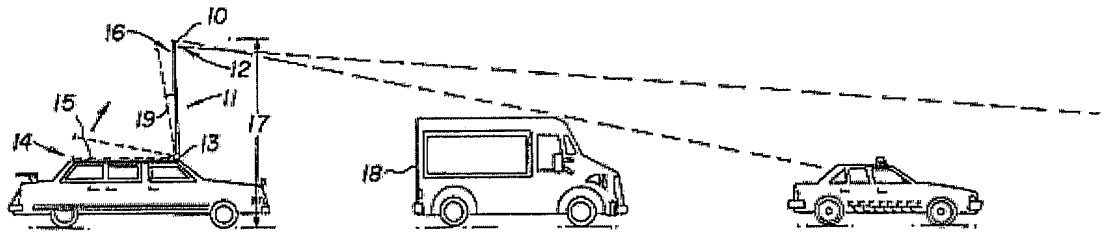


FIG. 1

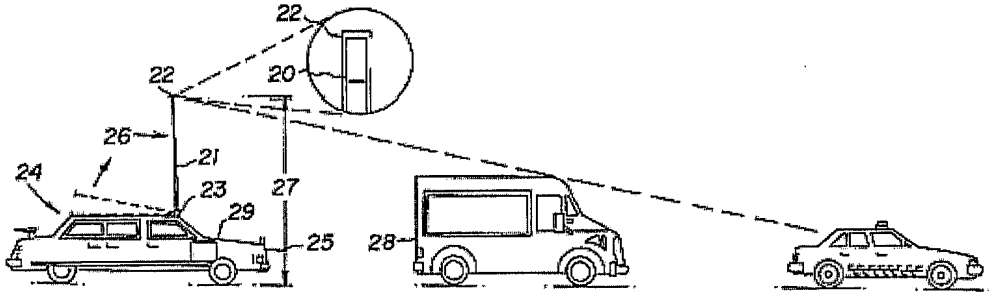


FIG. 2

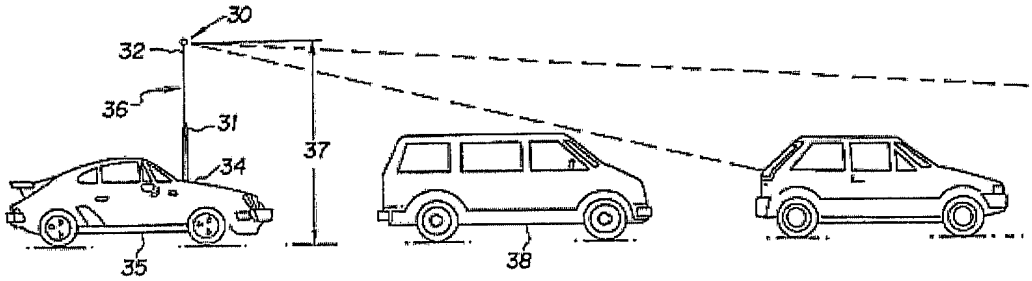


FIG. 3

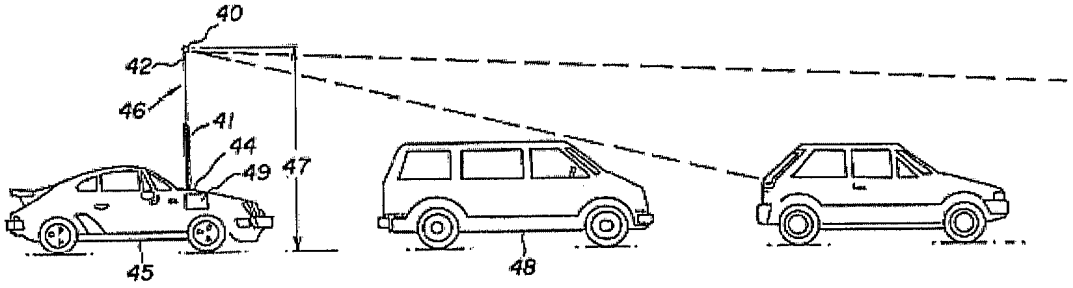


FIG. 4

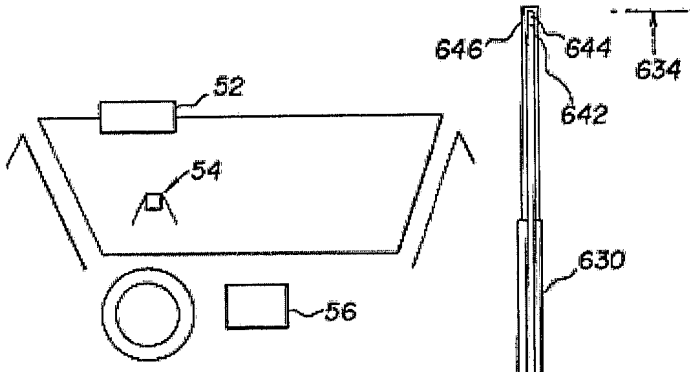


FIG. 5

FIG. 6

Applicant respectfully points out that the corresponding portion of O'Leary's Specification discloses:

> In a first embodiment, illustrated in FIG. 1, a miniaturized camera 10 is mounted on an end 12 opposite from a pivot 13 of a pivoting support 11 that is movable between a collapsed position 14, such as adjacent a roof line of the vehicle 15, to an erected position 16. In an erected position 16, the camera 10 is at a sufficient vertical height 17 to view over a vehicle 18 obstructing the driver's view of traffic. (Col. 3, lines 47-53).

In another embodiment, illustrated in FIG. 2, a fiber optic lens 20 associated with a camera 29 is mounted on an end 22 opposite from a pivot 23 of a pivoting support 21 that is movable between a collapsed position 24, such as adjacent a roof line of the vehicle 25, to an erected position 26. In an erected position 26, the fiber optic lens 20 is at a sufficient vertical height 27 to view over a vehicle 28 obstructing the driver's view of traffic. (Col. 3, lines 54-61).

For these pivoting support embodiments, it is also possible to provide for pivot 13, 23 to rotate perpendicularly sideways at an acute angle, as illustrated at 19, so as to view around traffic from the side. (Col. 3, lines 62-65).

In a third embodiment, illustrated in FIG. 3, a miniaturized camera 30 is mounted on the movable end 32 of a telescoping support 31 that is movable between a collapsed position, such as adjacent a wheel well 34 of the vehicle 35, to an erected position 36. In an erected position 36, the camera 30 is at a sufficient vertical height 37 to view over a vehicle 38 obstructing the driver's view of traffic. (Col. 3, lines 66-67; Col. 4, lines 1-5).

In yet another embodiment, illustrated in FIG. 4, a fiber optic lens 40 associated with a camera 49 is mounted on the movable end 42 of a telescoping support 41 that is movable between a collapsed position, such as adjacent a wheel well 44 of the vehicle 45, to an erected position 46. In an erected position 46, the fiber optic lens 40 is at a sufficient vertical height 47 to view over a vehicle 48 obstructing the driver's view of traffic. (Col. 4, lines 6-13).

For these telescoping embodiments, it is also possible to provide means for telescoping support 31, 41 to be selectively rotated about its vertical axis, so as to provide views in directions other than a forward-facing direction. This modification would be useful for when the system is employed for security or surveillance purposes. (Col. 4, lines 14-19).

In any of these embodiments, the image perceived by the camera may be sent to a display means by wired or wireless means. Within the vehicle, image processing/stablization means and cameras associated with a fiber optic lens can be located in any suitable location, including, but not limited to, a trunk, wheel well, ceiling, roof pillar, door pillar, door, firewall, engine compartment, rear deck, glove compartment, dashboard or under-seat location. (Col. 4, lines 20-28).

As illustrated in FIG. 5, the display means will typically be located conveniently for the driver to view, such as by a ceiling/windshield-mounted LCD 52, windshield-displayed HUD 54, or console/dash-

mounted navigation system CRT/LCD 56, although other displays and locations are also possible, including, but not limited to, a console-mounted thermal or inkjet printer display and an A-pillar, steering wheel or instrument panel display location. A driver wearable display, such as could be incorporated into a pair of eye glasses, could also be employed. The UV light 16 from the UV light source 12 is preferably constrained to specific boundaries. By confining the UV light to a specific area of the conveyor 13, the variations in intensity as a function of distance from the UV light source are minimized and therefore the dosage rate is substantially consistent for produce product 11 positioned at any point on the conveyor that is illuminated beneath the UV light source. The UV light is preferably constrained, as shown in FIG. 6, to an area of illumination 33 having the length L, and a width W. (Col. 4, lines 29-39).

An exemplary embodiment of the present invention is illustrated in FIG. 6. In this system, a video camera 610 having a CCD imaging means is mounted within a vehicle 620. Suitable locations include spaces within a trunk or a wheel well 622. A retractable mast 630, such as or similar to a standard telescoping power antenna is also mounted on the vehicle 620, preferably near the camera 610. The mast 630 can be connected 631 to the automobile radio and used, at a first height 632, as a radio antenna, and at a second height 634, for traffic perception. A fiber optic lens employing optical fiber 648, such as typically used in fiberscopes and borescopes, is preferably mounted on a reel 650, with a camera adapter lens 614 at one end mounted to the video camera 610 and the objective lens 642 and side-viewing tip adapter 644 attached to a tip portion 646 of the mast 630. As the mast 630 is extended, the optical fiber 648 unwinds from the reel 650 and are rewound when the mast 630 is retracted. Since the tip portion 646 of the mast will tend to oscillate in use on a highway, electronic image stabilization 660 can be incorporated into or downstream from camera 610. The stabilized image 670 is then displayed on the display means 680 for the driver to view. The erection and retraction of the support/mast in the present invention is accomplished by any suitable means and is preferably actuated by a switch provided near the driver. (Col. 4, lines 59-67; Col 5, lines 1-13).

See O'Leary *(U.S. Patent No.: 6,384,741, Col. 3, lines 47-6, Col. 4, lines 1-67, and Col. 5, lines 1-13).*

As can be seen from the foregoing, the Examiner-identified portions of O'Leary do *not recite* the text of clause [c] as recited in Independent Claim 1. For example, clause [c] recites "at least one reservoir in communication with said extensible finger."

Applicant has reviewed the Examiner-cited portions of O'Leary and is unable to locate a recitation of clause [c] of Claim 1. Applicant further respectfully points out that the Examiner has provided no evidence or reason as to why the text of the reference passages should be interpreted to teach clause [c] of Independent Claim 1 as the Examiner alleges.

Given that Applicant has shown, above, what O'Leary actually recites, the question thus naturally arises as to how Examiner saw O'Leary as teaching clause [c] of Independent Claim 1.

Applicant respectfully points out that the Applicant's Application is the only objective examiner-cited document of record that shows or suggests what Examiner purports the reference to teach. From this and O'Leary's express recitations (see above), it follows that Examiner is interpreting O'Leary through the lens of Applicant's application, which is impermissible hindsight use. Thus, at present, Examiner's assertions regarding O"Leary are untenable.

Accordingly, under the MPEP standards as set forth above, the Examiner has not established a prima facie case that art of record anticipates Independent Claim 1. Applicant respectfully asks Examiner to hold Independent Claim 1 allowable and to issue a Notice of Allowance of same.

2. Dependent Claims 2-3, 5, 10-11, 13-16, 23-26, and 34: Patentable for at Least Reasons of Dependency from Independent Claim 1

Claims 2-3, 5, 10-11, 13-16, 23-26, and 34 depend either directly or indirectly from Independent Claim 1. "A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers." *See* 35 U.S.C. § 112 paragraph 4. Consequently, Dependent Claims 2-3, 5, 10-11, 13-14, 23-26, and 34 are patentable for at least the reasons why Independent Claim 1 is patentable. Accordingly, Applicant respectfully requests that Examiner hold Dependent Claims 2-3, 5, 10-11, 13-16, 23-26, and 34 patentable for at least the foregoing reasons, and issue a Notice of Allowance on same.

D. Technical Material Cited by Examiner (Labbe (U.S. Patent No.: 4,944,659)) Does Not Recite the Text of Independent Claim 1 as Presented Herein; Notice of Allowance of Same Respectfully Requested

1. Independent Claim 1

Independent Claim 1 recites: "A device for perfusion management, comprising: a body portion; at least one extensible finger coupled to said body portion; at least one reservoir in communication with said extensible finger; and a control circuitry coupled to said extensible finger, and/or said body portion."

a) Technical Material Cited by Examiner Does Not Recite the Text of at Least Independent Claim 1.

As set forth above, Independent Claim 1 recites as follows: A device for perfusion management, comprising: [a] a body portion; [b] at least one extensible finger coupled to said body portion; [c] at least one reservoir in communication with said extensible finger; and [d] a control circuitry coupled to said extensible finger, and/or said body portion.[11]

With respect to Claim 1, Examiner has stated, "Claims 1-4, 8-9,17,20-21 and 25-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Labbe et al (USPN 4,944,659). Labbe discloses an implantatable piezoelectric pumping system that includes a body (housing), an extending part (catheter), at least one receiving body (drug reservoir), polymer (piezoelectric element) and a control circuit. See figures 3a-b." Examiner's Office Action, p. 3 (06 September 2007).

(1) Examiner Citations With Regard to Clause [b] of Independent Claim 1:

Applicant respectfully points out that Applicant has reviewed the portions of Labbe identified by Examiner, and so far as Applicant can discern, Labbe does not recite the text of clause [b] of Applicant's Independent Claim 1. Rather, the Figures 3a and 3b of Labbe cited by Examiner recite as follows:

[11] The lettering of the clauses herein is merely for sake of clarity of argument and should not be taken to imply any particular ordering of the clauses.

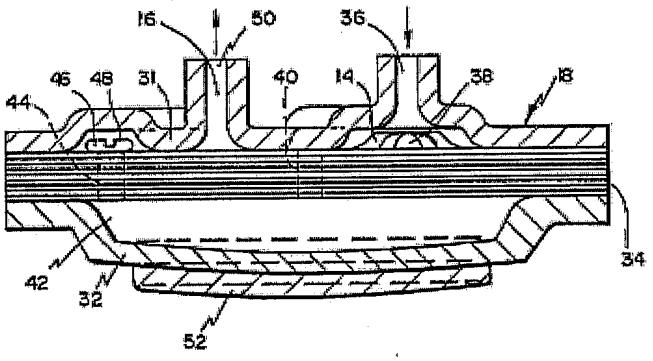


FIG. 3a

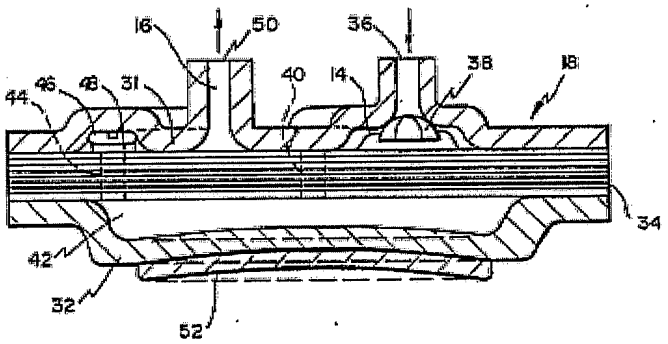


FIG. 3b

Applicant respectfully points out that the corresponding portion of Labbe's Specification discloses:

> The overall configuration of the implantable dispenser is shown in FIGS. 2 and 3a and 3b as comprising a septum 8 mounted in lobe portion 6 and containing a radially compressed block of silicone rubber, an inlet 9 being provided for external access and a passageway 10 to a main drug reservoir region 12. In use, the reservoir 12 is filled by insertion of the hypodermic needle of a syringe into the silicone rubber insert via a passageway 9, so that the drug flows into the main reservoir region 12 via a passageway 10. Extraction of the needle, when the reservoir is filled, automatically closes the silicone block. Valves 14, 16 are provided with, inlet value 14 permitting entry of the drug into a pump 18 and outlet value 16 permitting exit of the drug from the pump body to a delivery catheter 20, which extends from the dispenser body to a suitable location within the human body. The pump is connected to an electronic control circuit by means of electrical leads 24, the electronic circuit being powered by a battery 26. A gas spring is provided in the area 30 between the pump and the electronic

circuit 22 within the volume enclosed by a bellows 33. The function of the gas spring is to maintain an essentially constant pressure in reservoir 12 as the quantity of drug decreases during infusion. By selecting a suitable mixture of "Freon"-type hydrocarbons, which liquify at about one bar pressure, the pressure in the gas spring can be made to remain effectively constant (apart from the spring characteristics of the bellows) as the drug is used up and the bellows 33 opens. (Col. 3, lines 3-32).

The pump is shown in more detail in FIGS. 3a and 3b as being of generally flat and planar shape being 3.0 cm in diameter and 2 mm thick. The pump comprises two plate members 31, 32 of pressure molded titanium alloy and an intermediate plate 34 is also formed of titanium alloy. These plates define a port 36 for inlet valve 14 housing a freely movable valve member 38 and communicating with a passageway 40. Passageway 40 formed in intermediate plate 34 communicates with a pump chamber 42 and a further channel 44 formed in plate member 34 communicates with an outlet valve having a freely movable valve member 46 which is mounted in a recess 48 which communicates with outlet 50. (Col. 3, lines 33-45).

Titanium plate 32 defines a movable member to which is bonded a circular plane piezoelectric sheet 52. Suitable seals are provided (not shown) surrounding the valve members, the seals and valve members being made of biologically compatible materials, for example silicone rubber. The three plates 31, 32, 34 are sealed together by a technique such as electron beam welding or diffusion bonding. The piezoelectric element 52 is mounted on plate 32 using a conductive epoxy filled with silver. (Col. 3, lines 46-54).

In operation, when an electric voltage is applied across the thickness of the piezoelectric element 52, this creates a bowing, resulting in the central part of piezoelectric element moving out of the plane of the element a certain amount whereby a corresponding deformation in plate 32 and thus causing an expansion or contraction of volume of the pump chamber. Where expansion is caused, this creates a suction effect causing valve member 38 to be moved downwardly allowing drug from reservoir 12 to flow into the valve chamber. Outlet valve member 46 is maintained against passage 44 during this movement. Upon contraction of the space of the pump chamber caused by inward movement of plate 32, valve member 46 is pushed upward by permitting a drug to flow through the outlet valve 16. (Col. 3, lines 55-68; Col. 4, lines 1-2).

See Labbe *(U.S. Patent No.: 4,944,659, Figs. 3a and 3b, Col. 3, lines 3-68 and Col. 4, lines 1-2).*

As can be seen from the foregoing, the Examiner-identified portions of Labbe do *not recite* the text of clause [b] as recited in Independent Claim 1. For example, clause [b] recites "at least one extensible finger coupled to said body portion."

Applicant has reviewed the Examiner-cited portions of Labbe and is unable to locate a recitation of clause [b] of Claim 1. Applicant further respectfully points out that the Examiner has provided no evidence or reason as to why the text of the reference passages should be interpreted to teach clause [b] of Independent Claim 1 as the Examiner alleges.

Given that Applicant has shown, above, what Labbe actually recites, the question thus naturally arises as to how Examiner saw Labbe as teaching clause [b] of Independent Claim 1.

Applicant respectfully points out that the Applicant's Application is the only objective examiner-cited document of record that shows or suggests what Examiner purports the reference to teach. From this and Labbe's express recitations (see above), it follows that Examiner is interpreting Labbe through the lens of Applicant's application, which is impermissible hindsight use. Thus, at present, Examiner's assertions regarding Labbe are untenable.

Accordingly, under the MPEP standards as set forth above, the Examiner has not established a prima facie case that art of record anticipates Independent Claim 1. Applicant respectfully asks Examiner to hold Independent Claim 1 allowable and to issue a Notice of Allowance of same.

2. Dependent Claims 2-4, 8-9, 17, 20-21 and 25-33: Patentable for at Least Reasons of Dependency from Independent Claim 1

Claims 2-4, 8-9, 17, 20-21, and 25-33 depend either directly or indirectly from Independent Claim 1.. "A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers." *See* 35 U.S.C. § 112 paragraph 4. Consequently, Dependent Claims 2-4, 8-9, 17, and 25-33 are patentable for at least the reasons why Independent Claim 1 is patentable. Accordingly, Applicant respectfully requests that

Examiner hold Dependent Claims 2-4, 8-9, 17, 20-21, and 25-33 patentable for at least the foregoing reasons, and issue a Notice of Allowance on same.

E. Technical Material Cited by Examiner (Davison (U.S. Patent No.: 6,296,638)) Does Not Recite the Text of Independent Claim 1 as Presented Herein; Notice of Allowance of Same Respectfully Requested

1. Independent Claim 1

Independent Claim 1 recites: "A device for perfusion management, comprising: a body portion; at least one extensible finger coupled to said body portion; at least one reservoir in communication with said extensible finger; and a control circuitry coupled to said extensible finger, and/or said body portion."

a) Technical Material Cited by Examiner Does Not Recite the Text of at Least Independent Claim 1.

As set forth above, Independent Claim 1 recites as follows: A device for perfusion management, comprising: [a] a body portion; [b] at least one extensible finger coupled to said body portion; [c] at least one reservoir in communication with said extensible finger; and [d] a control circuitry coupled to said extensible finger, and/or said body portion.[12]

With respect to Claim 1, Examiner has stated, "Claims 1, 10, 12 and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Davison et al (USPN 6,296,638 Bl). Davison discloses a body (10), an extending part (catheter), at least one receiving body (34) and a control circuit. The system also includes a tool for ablating and cautery." Examiner's Office Action, p. 3 (06 September 2007).

(1) Examiner Citations With Regard to Clause [b] of Independent Claim 1:

[12] The lettering of the clauses herein is merely for sake of clarity of argument and should not be taken to imply any particular ordering of the clauses.

Applicant respectfully points out that Applicant has reviewed the portions of Davison identified by Examiner, and so far as Applicant can discern, Davison does not recite the text of clause [b] of Applicant's Independent Claim 1. Rather, the portions of Davison that recite body (10), catheter and connector 34 cited by the Examiner recite as follows:

> Referring now to FIG. 1, an exemplary electrosurgical system 5 for resection, ablation, coagulation and/or contraction of tissue will now be described in detail. As shown, electrosurgical system 5 generally includes an electrosurgical probe 20 connected to a power supply 10 for providing high frequency voltage to one or more electrode terminals and a loop electrode (not shown in FIG. 1) on probe 20. Probe 20 includes a connector housing 44 at its proximal end, which can be removably connected to a probe receptacle 32 of a probe cable 22. The proximal portion of cable 22 has a connector 34 to couple probe 20 to power supply 10. Power supply 10 has an operator controllable voltage level adjustment 38 to change the applied voltage level, which is 10 observable at a voltage level display 40. Power supply 10 also includes one or more foot pedals 24 and a cable 26 which is removably coupled to a receptacle 30 with a cable connector 28. The foot pedal 24 may also include a second pedal (not shown) for remotely adjusting the energy level applied to electrode terminals 104, and a third pedal (also not shown) for switching between an ablation mode and a coagulation mode. (Col. 17, lines 29-49).
>
> FIGS. 2-5 illustrate an exemplary electrosurgical probe 20 constructed according to the principles of the present invention. As shown in FIG. 2, probe 20 generally includes an elongated shaft 100 which may be flexible or rigid, a handle 204 coupled to the proximal end of shaft 100 and an electrode support member 102 coupled to the distal end of shaft 100. Shaft 100 preferably comprises an electrically conducting material, usually metal, which is selected from the group consisting of tungsten, stainless steel alloys, platinum or its alloys, titanium or its alloys, molybdenum or its alloys, and nickel or its alloys. Shaft 100 includes an electrically insulating jacket 108, which is typically formed as one or more electrically insulating sheaths or coatings, such as polytetrafluoroethylene, polyimide, and the like. The provision of the electrically insulating jacket over the shaft prevents direct electrical contact between these metal elements and any adjacent body structure or the surgeon. Such direct electrical contact between a body structure (e.g., tendon) and an exposed electrode could result in unwanted heating and necrosis of the structure at the point of contact causing necrosis. (Col. 17, lines 50-67; Col. 18, lines 1-3).

See Davison *(U.S. Patent No.: 6,086,638, Col. 17, lines 29-67 and Col. 18, lines 1-3).*

As can be seen from the foregoing, the Examiner-identified portions of Davison do *not recite* the text of clause [b] as recited in Independent Claim 1. For example, clause [b] recites "at least one extensible finger coupled to said body portion."

Applicant has reviewed the Examiner-cited portions of Davison and is unable to locate a recitation of clause [b] of Claim 1. Applicant further respectfully points out that the Examiner has provided no evidence or reason as to why the text of the reference passages should be interpreted to teach clause [b] of Independent Claim 1 as the Examiner alleges.

Given that Applicant has shown, above, what Davison actually recites, the question thus naturally arises as to how Examiner saw Davison as teaching clause [b] of Independent Claim 1.

Applicant respectfully points out that the Applicant's Application is the only objective examiner-cited document of record that shows or suggests what Examiner purports the reference to teach. From this and Davison's express recitations (see above), it follows that Examiner is interpreting Davison through the lens of Applicant's application, which is impermissible hindsight use. Thus, at present, Examiner's assertions regarding Davison are untenable.

Accordingly, under the MPEP standards as set forth above, the Examiner has not established a prima facie case that art of record anticipates Independent Claim 1. Applicant respectfully asks Examiner to hold Independent Claim 1 allowable and to issue a Notice of Allowance of same.

(2) Examiner Citations With Regard to Clause [c] of Independent Claim 1:

Applicant respectfully points out that Applicant has reviewed the portions of Davison identified by Examiner, and so far as Applicant can discern, Davison does not recite the text of clause [c] of Applicant's Independent Claim 1. Rather, the portions of Davison that recite body (10), catheter and connector 34 cited by the Examiner recite as follows:

> Referring now to FIG. 1, an exemplary electrosurgical system 5 for resection, ablation, coagulation and/or contraction of tissue will now be described in detail. As shown, electrosurgical system 5 generally includes an electrosurgical probe 20 connected to a power supply 10 for providing high frequency voltage to one or more electrode terminals and a loop electrode (not shown in FIG. 1) on probe 20. Probe 20 includes a connector housing 44 at its proximal end, which can be removably connected to a probe receptacle 32 of a probe cable 22. The proximal

> portion of cable 22 has a connector 34 to couple probe 20 to power supply 10. Power supply 10 has an operator controllable voltage level adjustment 38 to change the applied voltage level, which is 10 observable at a voltage level display 40. Power supply 10 also includes one or more foot pedals 24 and a cable 26 which is removably coupled to a receptacle 30 with a cable connector 28. The foot pedal 24 may also include a second pedal (not shown) for remotely adjusting the energy level applied to electrode terminals 104, and a third pedal (also not shown) for switching between an ablation mode and a coagulation mode. (Col. 17, lines 29-49).
>
> FIGS. 2-5 illustrate an exemplary electrosurgical probe 20 constructed according to the principles of the present invention. As shown in FIG. 2, probe 20 generally includes an elongated shaft 100 which may be flexible or rigid, a handle 204 coupled to the proximal end of shaft 100 and an electrode support member 102 coupled to the distal end of shaft 100. Shaft 100 preferably comprises an electrically conducting material, usually metal, which is selected from the group consisting of tungsten, stainless steel alloys, platinum or its alloys, titanium or its alloys, molybdenum or its alloys, and nickel or its alloys. Shaft 100 includes an electrically insulating jacket 108, which is typically formed as one or more electrically insulating sheaths or coatings, such as polytetrafluoroethylene, polyimide, and the like. The provision of the electrically insulating jacket over the shaft prevents direct electrical contact between these metal elements and any adjacent body structure or the surgeon. Such direct electrical contact between a body structure (e.g., tendon) and an exposed electrode could result in unwanted heating and necrosis of the structure at the point of contact causing necrosis. (Col. 17, lines 50-67; Col. 18, lines 1-3).

See Davison *(U.S. Patent No.: 6,086,638, Col. 17, lines 29-67 and Col. 18, lines 1-3).*

As can be seen from the foregoing, the Examiner-identified portions of Davison do *not recite* the text of clause [c] as recited in Independent Claim 1. For example, clause [c] recites "at least one reservoir in communication with said extensible finger."

Applicant has reviewed the Examiner-cited portions of Davison and is unable to locate a recitation of clause [c] of Claim 1. Applicant further respectfully points out that the Examiner has provided no evidence or reason as to why the text of the reference passages should be interpreted to teach clause [c] of Independent Claim 1 as the Examiner alleges.

Given that Applicant has shown, above, what Davison actually recites, the question thus naturally arises as to how Examiner saw Davison as teaching clause [c] of Independent Claim 1.

Applicant respectfully points out that the Applicant's Application is the only objective examiner-cited document of record that shows or suggests what Examiner purports the reference to teach. From this and Davison's express recitations (see above), it follows that Examiner is interpreting Davison through the lens of Applicant's application, which is impermissible hindsight use. Thus, at present, Examiner's assertions regarding Davison are untenable.

Accordingly, under the MPEP standards as set forth above, the Examiner has not established a prima facie case that art of record anticipates Independent Claim 1. Applicant respectfully asks Examiner to hold Independent Claim 1 allowable and to issue a Notice of Allowance of same.

2. Dependent Claims 10, 12, 18-19: Patentable for at Least Reasons of Dependency from Independent Claim 1

Claims 10, 12, 18-19 depend either directly or indirectly from Independent Claim 1. "A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers." *See* 35 U.S.C. § 112 paragraph 4. Consequently, Dependent Claims 10, 12, 18-19 are patentable for at least the reasons why Independent Claim 1 is patentable. Accordingly, Applicant respectfully requests that Examiner hold Dependent Claims 10, 12, 18-19 patentable for at least the foregoing reasons, and issue a Notice of Allowance on same.

F. Technical Material Cited by Examiner (Adair (U.S. Patent No.: 6,296,638)) Does Not Recite the Text of Independent Claim 1 as Presented Herein; Notice of Allowance of Same Respectfully Requested

1. Independent Claim 1

Independent Claim 1 recites: "A device for perfusion management, comprising: a body portion; at least one extensible finger coupled to said body portion; at least one reservoir in communication with said extensible finger; and a control circuitry coupled to said extensible finger, and/or said body portion."

a) Technical Material Cited by Examiner Does Not Recite the Text of at Least Independent Claim 1.

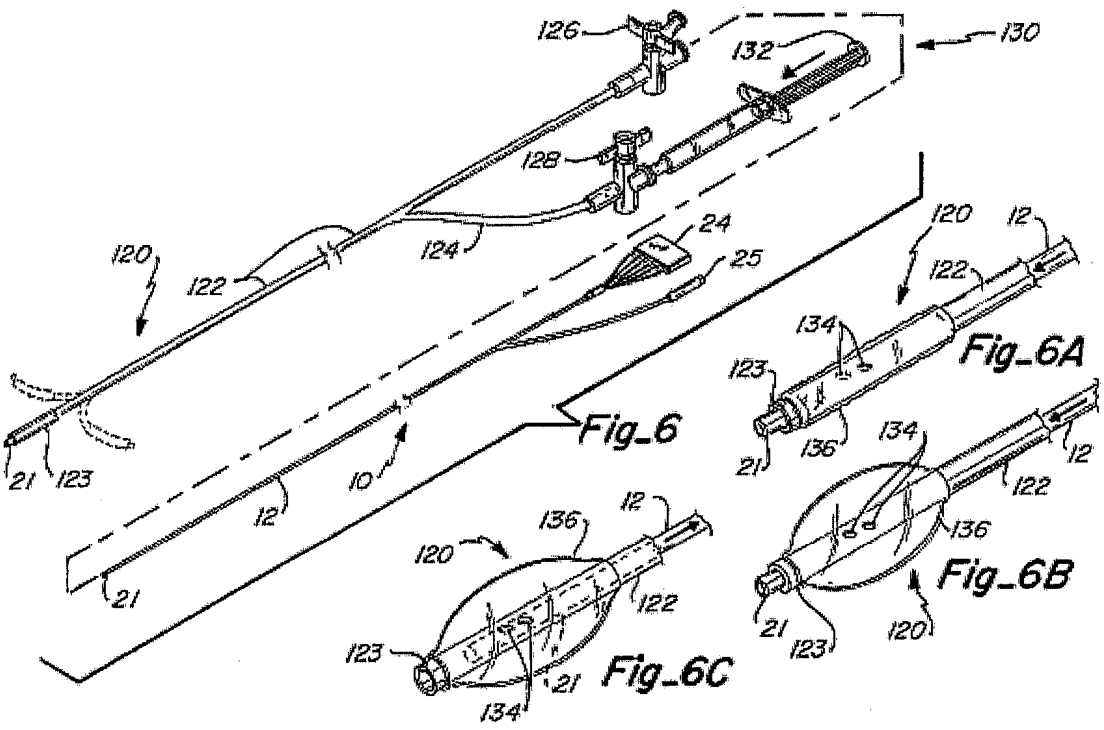
As set forth above, Independent Claim 1 recites as follows: A device for perfusion management, comprising: [a] a body portion; [b] at least one extensible finger coupled to said body portion; [c] at least one reservoir in communication with said extensible finger; and [d] a control circuitry coupled to said extensible finger, and/or said body portion.[13]

With respect to Claim 1, Examiner has stated, "Claims 1 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Adair (USPN 6,086,528). Adair discloses a body (handle), an extending part (probe), at least one receiving body (syringe) and a control circuit. The system also includes a stent delivery. See figure 6." Examiner's Office Action, p. 3 (06 September 2007).

(1) Examiner Citations With Regard to Clause [b] of Independent Claim 1:

Applicant respectfully points out that Applicant has reviewed the portions of Adair identified by Examiner, and so far as Applicant can discern, Adair does not recite the text of clause [b] of Applicant's Independent Claim 1. Rather, Figure 6 of Adair cited by Examiner recites as follows:

[13] The lettering of the clauses herein is merely for sake of clarity of argument and should not be taken to imply any particular ordering of the clauses.



Applicant respectfully points out that the corresponding portion of Adair's Specification discloses:

> In yet another application, the microendoscope 10 may be used in conjunction with a balloon catheter 120. The balloon catheter 120 shown in FIG. 6 is of a type used within very small bodily passages such as the urethra or the like. The balloon catheter 120 may include an elongate guide tube 122 having a distal end 123 which may be non-steerable, or steerable by guide wires (not shown) and a steering unit (not shown) which controls the guide wires as understood by those skilled in the art. The free or proximal end of air inflation port 124 connects to stop cock 128 which in turn connects to syringe 130. A very small diameter air inflation line (not shown) may be formed interiorly of guide tube 122 and connect between port 124 and openings 134. When the plunger 132 of the syringe is depressed, air is forced through air inflation port 124, through the small inflation line (not shown) and through openings 134 to inflate the balloon 136. Stop cock 128 may be positioned to prevent the back flow of air into the syringe 130 thus keeping the balloon inflated. As also shown in FIG. 6, guide tube 122 may further include its own stop cock 126 positioned at the proximal end thereof in order that the guide tube 122 may also introduce liquids or gas simultaneously with the endoscope. Supply tubes (not shown) can supply the appropriate liquids or gas through stop cock 126. (Col. 8, lines 44-67).

See Adair *(U.S. Patent No.: 6,086,528, Col. 8, lines 44-67).*

As can be seen from the foregoing, the Examiner-identified portions of Davison do *not recite* the text of clause [b] as recited in Independent Claim 1. For example, clause [b] recites "at least one extensible finger coupled to said body portion."

Applicant has reviewed the Examiner-cited portions of Adair and is unable to locate a recitation of clause [b] of Claim 1. Applicant further respectfully points out that the Examiner has provided no evidence or reason as to why the text of the reference passages should be interpreted to teach clause [b] of Independent Claim 1 as the Examiner alleges.

Given that Applicant has shown, above, what Adair actually recites, the question thus naturally arises as to how Examiner saw Adair as teaching clause [b] of Independent Claim 1.

Applicant respectfully points out that the Applicant's Application is the only objective examiner-cited document of record that shows or suggests what Examiner purports the reference to teach. From this and Adair's express recitations (see above), it follows that Examiner is interpreting Adair through the lens of Applicant's application, which is impermissible hindsight use. Thus, at present, Examiner's assertions regarding Adair are untenable.

Accordingly, under the MPEP standards as set forth above, the Examiner has not established a prima facie case that art of record anticipates Independent Claim 1. Applicant respectfully asks Examiner to hold Independent Claim 1 allowable and to issue a Notice of Allowance of same.

(2) Examiner Citations With Regard to Clause [d] of Independent Claim 1:

Applicant respectfully points out that Applicant has reviewed the portions of Adair identified by Examiner, and so far as Applicant can discern, Adair does not recite the text of clause [d] of Applicant's Independent Claim 1. Rather, Figure 6 of Adair cited by Examiner recites as follows:

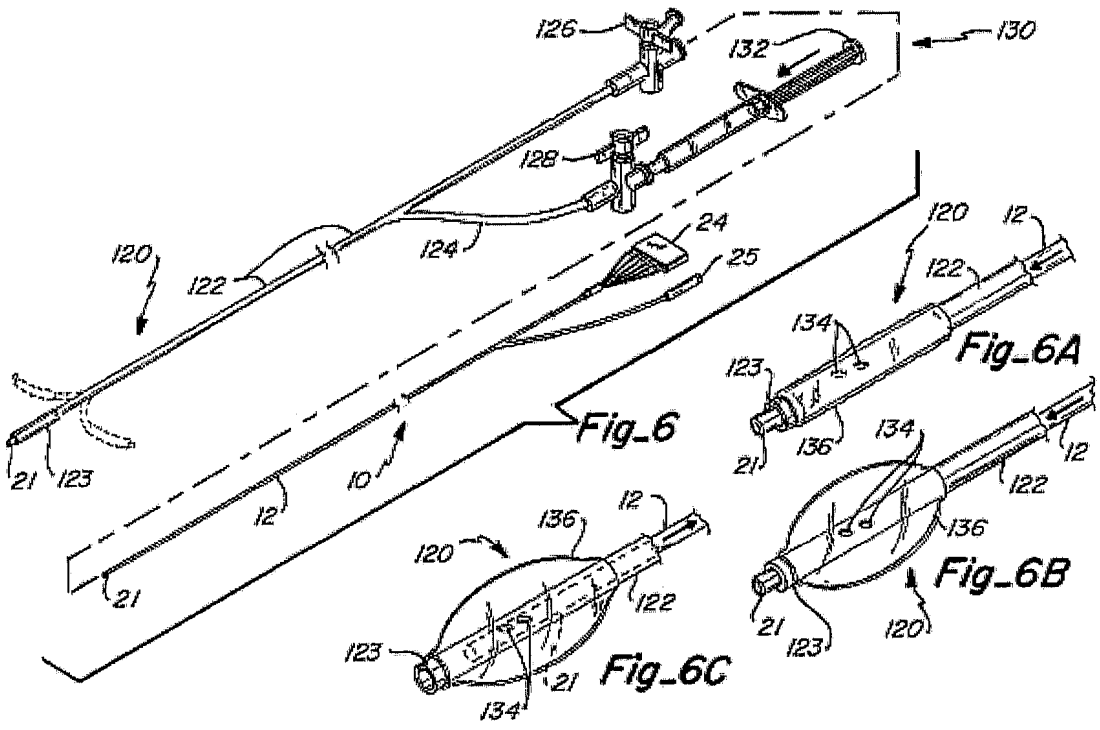


Fig_6

Fig_6A

Fig_6B

Fig_6C

Applicant respectfully points out that the corresponding portion of Adair's Specification discloses:

> In yet another application, the microendoscope 10 may be used in conjunction with a balloon catheter 120. The balloon catheter 120 shown in FIG. 6 is of a type used within very small bodily passages such as the urethra or the like. The balloon catheter 120 may include an elongate guide tube 122 having a distal end 123 which may be non-steerable, or steerable by guide wires (not shown) and a steering unit (not shown) which controls the guide wires as understood by those skilled in the art. The free or proximal end of air inflation port 124 connects to stop cock 128 which in turn connects to syringe 130. A very small diameter air inflation line (not shown) may be formed interiorly of guide tube 122 and connect between port 124 and openings 134. When the plunger 132 of the syringe is depressed, air is forced through air inflation port 124, through the small inflation line (not shown) and through openings 134 to inflate the balloon 136. Stop cock 128 may be positioned to prevent the back flow of air into the syringe 130 thus keeping the balloon inflated. As also shown in FIG. 6, guide tube 122 may further include its own stop cock 126 positioned at the proximal end thereof in order that the guide tube 122 may also introduce liquids or gas simultaneously with the endoscope. Supply tubes (not shown) can supply the appropriate liquids or gas through stop cock 126. (Col. 8, lines 44-67).

See Adair *(U.S. Patent No.: 6,086,528, Col. 8, lines 44-67).*

As can be seen from the foregoing, the Examiner-identified portions of Davison do *not recite* the text of clause [d] as recited in Independent Claim 1. For example, clause [d] recites "a control circuitry coupled to said extensible finger, and/or said body portion."

Applicant has reviewed the Examiner-cited portions of Adair and is unable to locate a recitation of clause [d] of Claim 1. Applicant further respectfully points out that the Examiner has provided no evidence or reason as to why the text of the reference passages should be interpreted to teach clause [d] of Independent Claim 1 as the Examiner alleges.

Given that Applicant has shown, above, what Adair actually recites, the question thus naturally arises as to how Examiner saw Adair as teaching clause [d] of Independent Claim 1.

Applicant respectfully points out that the Applicant's Application is the only objective examiner-cited document of record that shows or suggests what Examiner purports the reference to teach. From this and Adair's express recitations (see above), it follows that Examiner is interpreting Adair through the lens of Applicant's application, which is impermissible hindsight use. Thus, at present, Examiner's assertions regarding Adair are untenable.

Accordingly, under the MPEP standards as set forth above, the Examiner has not established a prima facie case that art of record anticipates Independent Claim 1. Applicant respectfully asks Examiner to hold Independent Claim 1 allowable and to issue a Notice of Allowance of same.

2. Dependent Claim 22: Patentable for at Least Reasons of Dependency from Independent Claim 1

Claim 22 depends directly from Independent Claim 1. "A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers." *See* 35 U.S.C. § 112 paragraph 4. Consequently, Dependent Claim 22 is patentable for at least the reasons why Independent Claim 1 is patentable. Accordingly, Applicant respectfully requests that Examiner hold Dependent Claim 22 patentable for at least the foregoing reasons, and issue a Notice of Allowance on same.

G. Double Patenting Rejections

1. Nonstatutory-Type Double Patenting Rejections of Claims 1-34.

Examiner stated, "Claims 1-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-37 of copending Application No. 10/827,576..." *See Examiner's Office Action*, p. 4 (06 September 2007).

Responsive to Examiner, Applicant is filing herewith a first terminal disclaimer with respect to Claims 1-34. Applicant notes for the record that although Applicant is filing a terminal disclaimer herewith, Applicant expressly does NOT agree with Examiner regarding the rejection of Claims 1-34 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-37 of copending Application No. 10/827,576. The filing of such terminal disclaimer should not be taken as an admission of any sort nor should such filing be taken as acquiescence in Examiner's assertion regarding any "non-statutory obviousness-type double patenting." Applicant does believe the claims are patentable over Claims 1-37 of co-pending Application No. 10/827,576 and is merely filing the Terminal Disclaimer to advance prosecution. Accordingly, Applicants respectfully request the Examiner to withdraw the rejections of the claims.

Furthermore, Examiner stated, "Claims 1-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over...claims 1-41 of copending Application No. 10/827,390." *See Examiner's Office Action*, p. 4 (06 September 2007).

Responsive to Examiner, Applicant is filing herewith a second terminal disclaimer with respect to Claims 1-34. Applicant notes for the record that although Applicant is filing a terminal disclaimer herewith, Applicant expressly does NOT agree with Examiner regarding the rejection of Claims 1-34 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-41 of copending Application No. 10/827,390. The filing of such terminal disclaimer should not be taken as an admission of any sort nor should such filing be taken as acquiescence in Examiner's assertion regarding any "non-statutory obviousness-type double patenting." Applicant does believe the claims are patentable over Claims 1-41 of copending Application No. 10/827,390, and is merely filing the Terminal Disclaimer to advance

prosecution. Accordingly, Applicants respectfully request the Examiner to withdraw the rejections of the claims.

IV. CONCLUSION

Applicant may have during the course of prosecution cancelled and/or amended one or more claims. Applicant notes that any such cancellations and/or amendments will have transpired (i) prior to issuance and (ii) in the context of the rules that govern claim interpretation during prosecution before the United States Patent and Trademark Office (USPTO). Applicant notes that the rules that govern claim interpretation during prosecution form a radically different context than the rules that govern claim interpretation subsequent to a patent issuing. Accordingly, Applicant respectfully submits that any cancellations and/or amendments during the course of prosecution should be held to be tangential to and/or unrelated to patentability in the event that such cancellations and/or amendments are viewed in a post-issuance context under post-issuance claim interpretation rules.

Insofar as that the Applicant may have during the course of prosecution cancelled/amended claims sufficient to obtain a Notice of Allowability of all claims pending, Applicant may not have during the course of prosecution explicitly addressed all rejections and/or statements in Examiner's Office Actions. The fact that rejections and/or statements may not be explicitly addressed during the course of prosecution should NOT be taken as an admission of any sort, and Applicant hereby reserves any and all rights to contest such rejections and/or statements at a later time. Specifically, no waiver (legal, factual, or otherwise), implicit or explicit, is hereby intended (e.g., with respect to any facts of which Examiner took Official Notice, and/or for which Examiner has supplied no objective showing, Applicant hereby contests those facts and requests express documentary proof of such facts at such time at which such facts may become relevant). For example, although not expressly set forth during the course of prosecution, Applicant continues to assert all points of (e.g. caused by, resulting from, responsive to, etc.) any previous Office Action, and no waiver (legal, factual, or otherwise), implicit or explicit, is hereby intended. Specifically, insofar as that Applicant does not consider the cancelled/unamended claims to be unpatentable, Applicant hereby gives notice that it may intend

to file and/or has filed a continuing application in order prosecute such cancelled/unamended claims.

With respect to any cancelled claims, such cancelled claims were and continue to be a part of the original and/or present patent application(s). Applicant hereby reserves all rights to present any cancelled claim or claims for examination at a later time in this or another application. Applicant hereby gives public notice that any cancelled claims are still to be considered as present in all related patent application(s) (e.g. the original and/or present patent application) for all appropriate purposes (e.g., written description and/or enablement). Applicant does NOT intend to dedicate the subject matter of any cancelled claims to the public.

The Examiner is invited to contact Elliott Y. Chen at (206) 315-7914, or Dale R. Cook at (425) 467-2260 with any issues that may advance prosecution of the application on the merits.

Respectfully submitted,

3/6/2008

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